PETITION FOR EXTENSION OF TIME

Applicants petition for a two-month extension of time for a response to an Office Action which was due on January 22, 2003, up to and including March 22, 2003. Since March 22, 2003 falls on a Saturday, submission of the response on the next business day in the United States Patent Office, on Monday March 24, 2003 is therefore considered timely.

The Commissioner is hereby authorized to charge the requisite fee for small entity to Deposit Account No. 23-1703.

Please consider the following amendment.

IN THE SPECIFICATION:

On page 4, line 28, the full sentence is as follows:

C1 An aliquot of the emulsion may contain about 0.5 mg/ml of conjugate.

IN THE CLAIMS:

Please cancel claims 36, 37, 39, 42, and 45, without prejudice.

Please consider the following amended claims:

35. An immunogenic composition formulated as an emulsion which is stable in frozen storage comprising an aqueous phase immunogen and a pharmaceutically acceptable oily vehicle selected from the group consisting of the Montanide type ISA 25, ISA 703, ISA 719, and ISA 720, without an additional emulsion stabilizer; the thawed composition retaining at least 60% of the emulsion globules at a size of less than 1 μm and exhibiting a normal release rate of the immunogen.

C2

38. The immunogenic composition as claimed in claim 35, wherein the emulsion is formulated as a mixture of the oily vehicle and the aqueous phase immunogen so as to form an oil-in-water or water-in-oil emulsion.

C3

40. The immunogenic composition as claimed in claim 35, wherein the oily vehicle is Montanide type ISA 703.

41. The immunogenic composition as claimed in claim 35 or 53, wherein the frozen storage can last at least one year.

44. The immunogenic composition as claimed in anyone of the claims 35, 40, 41, 43, and 53, wherein the composition comprises significantly increased immunogenicity after one freezing-thawing cycle.

46. The method as claimed in claim 48, wherein the immunogen comprises a synthetic immunomimic peptide conjugated to an immunogenic carrier component.

47. The method as claimed in claim 46 or 48 wherein the peptide comprises an epitope of gastrin 17 (G17), gastrin 34 (G34), or GnRH.

48. A method for formulating an immunogenic composition stable in frozen storage comprising:

preparing an immunogenic emulsion by mixing an aqueous phase immunogen comprising an immunogenic carrier conjugated to an immunomimic peptide, with a pharmaceutically acceptable oily vehicle so as to form a stable frozen storage oil-in-water or water-in-oil formulation, wherein the oily vehicle is selected from the group consisting of a Montanide type ISA 25, ISA 703, ISA 719 and ISA 720 without an additional emulsion stabilizer; the thawed composition retaining at least 60% of the emulsion globules at a size of less than 1 μm and exhibiting a normal release rate of the immunogen.

49. The method as claimed in claim 48, wherein the frozen storage stability of the immunogenic emulsion comprises a prolonged integrity of the immunogen.

Please consider the following new claims 53-72:

-- 53. An immunogenic composition formulated as an oil-in-water or water-in-oil emulsion which is stable in frozen storage comprising an aqueous phase immunogenic carrier conjugated to a G17 immunomimic peptide and a pharmaceutically acceptable oily vehicle at a ratio of 30:70, consisting of Montanide type ISA 703, without an additional emulsion stabilizer; the thawed composition retaining at least 60% of the emulsion globules at a size of less than 1 μm and exhibiting a normal release rate of the immunogen.--

-- 54. The immunogenic composition of claim 35 or 53, wherein the immunogen remains substantially intact after prolonged frozen storage.--

-- 55. The immunogenic composition of claim 35 or 53, wherein the integrity of the immunogen is not significantly affected after one or more freeze-thaw cycles.--

-- 56. The immunogenic composition of claim 35 or 53, wherein at least about 97% of the emulsion maintains a globule size of less than 1 μm after five successive freeze-thaw cycles.--

-- 57. The immunogenic composition of claim 35 or 53, wherein the immunogen release rate from the emulsion is not significantly altered by long-term frozen storage.--

-- 58. The immunogenic composition of claim 35 or 53, wherein the immunogen is a synthetic immunomimic peptide conjugated to an immunogenic carrier.--

-- 59. The immunogenic composition as claimed in anyone of the claims 35, 53 and 54, wherein the composition is stored at about -18°C to about -80°C.--

-- 60. The immunogenic composition as chaimed in anyone of the claims 35, 53 and 54, wherein the composition is stored at about -18°C to about -23°C.--

-- 61. The immunogenic composition as claimed in anyone of the claims 35, 53 and 54, wherein the composition is stored at about -70°C.--

-- 62. A method for formulating an immunogenic composition stable in frozen storage comprising preparing an immunogenic oil-in-water and water-in-oil emulsion by mixing an aqueous phase immunogen comprising an immunogenic carrier conjugated to a G17 immunomimic peptide with a pharmaceutically acceptable oily vehicle consisting of a Montanide type ISA 703 without an additional emulsion stabilizer; the thawed composition retaining at least 60% of the emulsion globules at a size of less than 1 μm and exhibiting a normal release rate of the immunogen.--

-- 63. The method as claimed in claim 48 or 62, wherein the immunogen comprises significant gain of immunogenicity.--

-- 64. The method as claimed in claim 48 or 62, wherein at least about 97% of the emulsion maintains a globule size of less than 1 μm after five successive freeze-thaw cycles.--

C1 -- 65. The method as claimed in claim 48 or 62, wherein the composition is stored at about -18°C to about -80°C.--

-- 66. The method as claimed in claim 48 or 62 wherein the composition is stored at about -18°C or about -23°C.--

-- 67. The method as claimed in claim 48 or 62, wherein the composition is stored at about -70°C.--

-- 68. A method for stable storage of an immunogenic emulsion comprising storing at a temperature ranging from about -18°C to about - 80°C an aqueous phase immunogenic carrier conjugated to an immunomimic peptide in a mixture with an oily vehicle selected from the group consisting of a Montanide type ISA 25, ISA 703, ISA 719, and ISA 720 without an additional emulsion stabilizer; the thawed emulsion retaining at least 60% of the emulsion globules at a size of less than 1 μm and exhibiting a normal release rate of the immunogen.--

-- 69. The method as claimed in claim 68, wherein the immunogenic carrier comprises diphtheria toxoid, tetanus toxoid, keyhole limpet hemocyanin, horseshoe crab hemocyanin, bovine serum albumin, ovalbumin, dextran, or immunogenic fragments thereof or a solvent extract of Amycolate or H. Pertussis.–

-- 71. The method as claimed in claim 68, wherein the immunomimic peptide comprises an epitope of gastrin 17, gastrin 34 or GnRH.--

-- 72. The method as claimed in claim 68, wherein the oily vehicle is the Montanide type ISA 703.–